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Queen Thomas
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Signature

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Applicant: Jeffry D. Watkins and James D. Pancock

Serial No.: PCT/US2003/038684

Filed: December 4, 2003

For: Butyrylcholinesterase Variants that Alter the
Activity of Chemotherapeutic Agents

Docket No.: X-16700B

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provide a copy of each of the listed documents for consideration by the Examiner, with the exception of unpublished US applications (references AL, AO, and AP) to which the Examiner has ready access.

Because this Statement is being filed in accordance with 37 C.F.R. 1.97(b),
Applicants submit that no additional fee is required.

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Applicants request consideration of this information.

Respectfully submitted,

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May 12, 2005

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION		First Applicant Jeffry Dean Watkins et al.	
		Filing Date December 4, 2003	Group

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Pages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US 5,264,563	November 23, 1993	Huse	
	AB	US 5,399,346	March 21, 1995	Anderson et al.	
	AC	US 5,460,959	October 24, 1995	Mulligan et al.	
	AD	US 5,506,125	April 9, 1996	McCabe et al.	
	AE	US 5,523,388	June 4, 1996	Huse	
	AF	US 5,580,859	December 3, 1996	Felgner et al.	
	AG	US 5,589,466	December 31, 1996	Felgner et al.	
	AH	US 5,620,896	April 15, 1997	Herrmann et al.	
	AI	US 5,643,578	July 1, 1997	Robinson et al.	
	AJ	US 5,656,465	August 12, 1997	Panicali et al.	
	AK	US 5,830,721	November 3, 1998	Stemmer et al.	
	AL	US SN 10/032,233	Filed December 20, 2001	Watkins et al.	
	AM	US 2004/0120939 A1	June 24, 2004	Watkins et al.	
	AN	US 2004/0121970 A1	June 24, 2004	Watkins et al.	
	AO	US SN 09/748,739	Filed December 26, 2000	Lockridge et al.	

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	AP	US SN 10/728,723	Filed December 4, 2003	Watkins et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ Kind Code ⁵ (if known)				
	BA	EP 0 779 365 A2	June 18, 1997			
	BB	WO 97/09441	March 13, 1997			
	BC	WO 97/10343	March 20, 1997			

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T ⁶
	CA	BAGSHAWE, K.D., "Antibody-Directed Enzyme Prodrug Therapy for Cancer: Its Theoretical Basis and Application." <u>Mol. Med. Today</u> 1:424-431, 1995.	
	CB	BARKER and SALEHI, "The MAGE proteins: emerging roles in cell cycle progression, apoptosis, and neurogenetic disease." <u>J. Neurosci. Res.</u> 67:705-712, 2002.	
	CC	BEAUFAY et al., "Analytical study of microsomes and isolated subcellular membranes from rat liver. I. Biochemical methods." <u>J. Cell. Biol.</u> 61:188-200, 1974.	
	CD	BETHKE, B and SAUER, B., "Segmental Genomic Replacement by Cre-mediated Recombination: Genotoxic Stress Activation of the p53 Promoter in Single-Copy Transformants." <u>Nucl. Acids Res.</u> , 25:2828-2834, 1997.	
	CE	BLONDELLE et al., "Soluble Combinatorial Libraries of Organic, Peptidomimetic and Peptide Diversities." <u>Trends Anal. Chem.</u> 14:83-92, 1995.	
	CF	BLONG, R. et al., "Tetramerization Domain of Human Butyrylcholinesterase is at the C-terminus." <u>Biochem J.</u> 327 (Pt 3): 747-757, 1997.	
	CG	BOOKMAN, M.A., "Biological therapy of ovarian cancer: current directions." <u>Semin. Oncol.</u> 25(3):381-396, 1998.	
	CH	BREM, H. et al., "Interstitial chemotherapy with drug polymer implants for the treatment of recurrent gliomas." <u>J. Neurosurg.</u> 74(3):441-446, 1991.	
	CI	CHERRY, C. and VACCHIANO, S., "Ovarian Cancer Screening and Prevention." <u>Seminars in Oncology Nursing</u> 18:167-173, 2002.	
	CJ	COUNTOURIOTIS, A. et al., "Cell surface antigen and molecular targeting in the treatment of hematologic malignancies." <u>Stem Cells</u> 20(3):215-229, 2002.	

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	CK	CRAMERI A. et al., "DNA Shuffling of a Family of Genes from Diverse Species Accelerates Directed Evolution." <u>Nature</u> 391:288-291, 1998.	
	CL	DODDS, H.M. and RIVORY, L.P. "The Mechanism for the Inhibition of Acetylcholinesterases by Irinotecan (CPT-11)." <u>Mol. Pharmacol.</u> 56(6):1346-1353, 1999.	
	CM	DUCREUX et al., "Irinotecan in Metastatic Colorectal Cancer: Dose Intensification and Combination with New Agents, Including Biological Response Modifiers." <u>Ann. Oncol.</u> 14 Suppl 2: ii17-ii23, 2003.	
	CN	DYMECKI, S., "Flp Recombinase Promotes Site-Specific DNA Recombination in Embryonic Stem Cells and Transgenic Mice." <u>Proc. Natl. Acad. Sci. U.S.A.</u> 93:6191-6196, 1996.	
	CO	ECKER, D.J. and CROOKE, S.T., "Combinatorial drug discovery: which methods will produce the greatest value?" <u>Biotechnology</u> 13(4):351-360, 1995.	
	CP	FUKUSHIGE, S. and SAUER, B., "Genomic Targeting with a Positive-Selection <i>lox</i> Integration Vector Allows Highly Reproducible Gene Expression in Mammalian Cells." <u>Proc. Natl. Acad. Sci. U.S.A.</u> 89:7905-7909, 1992.	
	CQ	GLASER, S. et al., "Antibody Engineering by Codon-Based Mutagenesis in a Filamentous Phage Vector System." <u>J. Immunology</u> 149:3903-3913, 1992.	
	CR	GOODMAN and RO, <u>Peptidomimetics for Drug Design</u> , in "Burger's Medicinal Chemistry and Drug Discovery" Vol. 1 (ed. M.E. Wolff; John Wiley & Sons 1995), page 803.	
	CS	GORDON, E.M. et al., "Applications of combinatorial technologies to drug discovery. 2. Combinatorial organic synthesis, library screening strategies, and future directions." <u>J. Med. Chem.</u> 37(10):1385-1401, 1994.	
	CT	HARE, C.B. et al., "Therapeutic efficacy of the topoisomerase I inhibitor 7-ethyl-10-(4-[1-piperidino]-1-piperidino)-carbonyloxy-camptothecin against pediatric and adult central nervous system tumor xenografts." <u>Cancer Chemother. Pharmacol.</u> 39(3):187-191, 1997.	

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	CU	HAREL, M. et al., "Conversion of Acetylcholinesterase to Butyrylcholinesterase: Modeling and Mutagenesis." <u>Proc. Nat. Acad. Sci. USA</u> 89: 10827-10831, 1992.	
	CV	HOESS, R.H. et al., "The role of the <i>loxP</i> spacer region in P1 site-specific recombination." <u>Nucleic Acids Res.</u> 14(5):2287-2300, 1986.	
	CW	HUMERICKHOUSE, R. et al., "Characterization of CPT-11 hydrolysis by human liver carboxylesterase isoforms hCE-1 and hCE-2." <u>Cancer Res</u> 60(5): 1189-1192, 2000.	
	CX	INDAR, A. et al., "Current concepts in immunotherapy for the treatment of colorectal cancer." <u>J.R. Coll. Surg. Edinb.</u> 47(2):458-474, 2002.	
	CY	JUNG, M., "Antibody directed enzyme prodrug therapy (ADEPT) and related approaches for anticancer therapy." <u>Mini Rev. Med. Chem.</u> 1(4):399-407, 2001.	
	CZ	KANEKO, R. et al., "Amount of expression of the tumor-associated antigen L6 gene and transmembrane 4 superfamily member 5 gene in gastric cancers and gastric mucosa." <u>Am. J. Gastroenterol.</u> 96(12):3457-3458, 2001.	
	CAA	KOSMAS, C. et al., "Anti-CD20-based therapy of B cell lymphoma: state of the art." <u>Leukemia</u> 16(10):2004-2015, 2002.	
	CAB	KUNKEL, T., "Rapid and Efficient Site-specific Mutagenesis Without Phenotypic Selection." <u>Proc. Natl. Acad. Sci. USA</u> 82:488-492, 1985.	
	CAC	MASSON, P. et al., "Role of Aspartate 70 and Tryptophan 82 in Binding of Succinylthiocholine to Human Butyrylcholinesterase." <u>Biochemistry</u> 36:2266-2277, 1997.	
	CAD	MATHIJSEN, R.H. et al. "Clinical pharmacokinetics and metabolism of irinotecan (CPT-11)." <u>Clin Cancer Res</u> 7(8): 2182-2194, 2001.	
	CAE	MOERTEL, C.G. et al., "Phase II study of camptothecin (NSC-100880) in the treatment of advanced gastrointestinal cancer." <u>Cancer Chemother. Rep.</u> 56(1):95-101, 1972.	

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	CAF	MUGGIA, F.M. et al., "Phase I clinical trial of weekly and daily treatment with camptothecin (NSC-100880): correlation with preclinical studies." <u>Cancer Chemother. Rep.</u> 56(4):515-521, 1972.	
	CAG	PAVILLARD, V. et al., "Determinants of the cytotoxicity of irinotecan in two human colorectal tumor cell lines." <u>Cancer Chemother. Pharmacol.</u> 49(4): 329-335, 2002.	
	CAH	RAGUPATHI, G., "Carbohydrate antigens as targets for active specific immunotherapy." <u>Cancer Immunol. Immunother.</u> 43(3):152-157, 1996.	
	CAI	SAUER, B. AND HENDERSON, N., "Site-specific DNA Recombination in Mammalian Cells by the Cre recombinase of Bacteriophage P1." <u>Proc. Natl. Acad. Sci. USA</u> 85(14):5166-5170, 1988.	
	CAJ	SCHWARTZ et al., "Engineering of Human Cholinesterases Explains and Predicts Diverse Consequences of Administration of Various Drugs and Poisons." <u>Pharmac. Ther.</u> 67: 283-322	
	CAK	SEGAL-EIRAS, A. AND CROCE, M.V., "Breast cancer associated mucin: a review." <u>Allerg. Immunopath.</u> 25(4):176-181, 1997.	
	CAL	SENTER, P.D. et al., "The role of rat serum carboxylesterase in the activation of paclitaxel and camptothecin prodrugs." <u>Cancer Res.</u> 56(7):1471-1474, 1996.	
	CAM	SENTER, P.D., "Activation of prodrugs by antibody-enzyme conjugates: a new approach to cancer therapy." <u>FASEB J.</u> 4(2):188-193, 1990.	
	CAN	SHEA, L.D. et al., "DNA delivery from polymer matrices for tissue engineering." <u>Nature Biotechnology</u> 17(6):551-554, 1999.	
	CAO	SIEGALL, C, "Targeted therapy of carcinomas using BR96 sFv-PE40, a single-chain immunotoxin that binds to the Le(y) antigen." <u>Semin. Cancer Biol.</u> 6(5):289-295, 1995.	
	CAP	SOREQ, H. et al., "Excavations into the Active-site Gorge of Cholinesterases." <u>Trends Biochem. Sci.</u> 17(9): 353-358, 1992.	

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	CAQ	SRIVASTAVA, P.K., "Protein tumor antigens." <u>Curr. Opin. Immunol.</u> 3(5):654-658, 1991.	
	CAR	STEMMER, W.P., "Rapid evolution of a protein in vitro by DNA shuffling." <u>Nature</u> 370(6488):389-391, 1994.	
	CAS	STEMMER, W.P., "DNA shuffling by random fragmentation and reassembly: in vitro recombination for molecular evolution." <u>Proc. Natl. Acad. Sci. USA</u> 91(22):10747-10751, 1994.	
	CAT	WATINE, J. et al., "Carcinoembryonic antigen as an independent prognostic factor of recurrence and survival in patients resected for colorectal liver metastases: a systematic review." <u>Dis. Colon Rectum</u> 44(12):1791-1799, 2001.	
	CAU	WU, H. et al., "Humanization of a Murine Monoclonal Antibody By Simultaneous Optimization of Framework and CDR Residues." <u>J. Mol. Biol.</u> 294:151-162, 1999.	
	CAV	WU, H. et al., "Stepwise <i>in vitro</i> Affinity Maturation of Vitaxin, an $\alpha\beta_3$ -Specific Humanized mAb." <u>Proc. Natl. Acad. Sci. USA</u> , 95:6037-6042, 1998.	
	CAW	XIE et al., "An Improved Cocaine Hydrolase: The A328Y Mutant of Human Butyrylcholinesterase is 4-Fold More Efficient," <u>Molecular Pharmacology</u> 55:83-91, 1999.	

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